

DEC 23 2002

**510(K) SUMMARY**

*K023341*

|                                |   |
|--------------------------------|---|
| Manufacturer:                  | Barco NV Barcovieu<br>Theodoor Sevenslaan 106<br>8500 Kortrijk<br>Belgium   |
| Submitted By:                  | Ferguson Medical<br>Consultant to Barco NV  |
| Contact Information:           | Phone: +32(0) 56 23 32 11<br>FAX: +32(0) 56 23 3 74   |
| Classification Name:           | System, image processing  |
| Common/Usual Name:             | Image display system, medical image<br>workstation, image monitor/display, and others   |
| Proprietary Name:              | Barco Coronis 5MP Medical Flat Panel Display<br>System  |
| Classification Number:         | 21 CFR 892.2050/Procode 90LLZ   |
| Substantial Equivalence:       | Barco NV Display Systems Coronis 3MP Medical<br>Flat Panel Display System (K013922)   |
| Device Description:            | The Coronis 5MP device is a digital image<br>display system   |
| Intended Use:                  | The Barco Coronis 5MP Medical Flat Panel<br>Display System is intended to be used in<br>displaying and viewing digital images for<br>review by trained medical practitioners. |
| Technological Characteristics: | The Barco Coronis 5MP device consists of<br>components to provide high resolution<br>visualization of digital images.   |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 23 2002

Barco NV BARCOVIEW  
% Mr. Frank Ferguson  
Official Correspondent  
Ferguson Medical  
P.O. Box 12038  
LA JOLLA CA 92039-2038

Re: K023341  
Trade/Device Name: Coronis 5MP Medical Flat  
Panel Display System  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: September 22, 2002  
Received: October 7, 2002

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

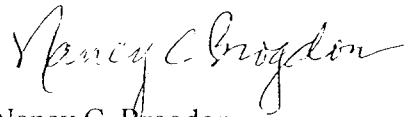
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

|                                  |                |
|----------------------------------|----------------|
| 8xx.1xxx                         | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx       | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx       | (301) 594-4654 |
| Other                            | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): K023341

Device Name: Coronis 5MP Medical Flat Panel Display System

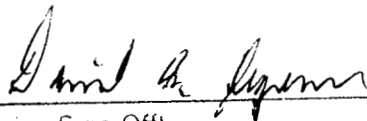
Indications For Use:

The Coronis 5MP Medical Flat Panel Display System is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K023341

Prescription Use XX  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_